

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on April 6, 2011 has been entered. The IDS filed on April 6, 2011 has been considered.

Claims 1-4, 6-7, 11, 14-19, 21-26 and 29-31 are allowed.

REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance: a liquid, aqueous composition comprising (i) a factor VII polypeptide; (ii) an agent suitable for keeping pH in the range of from about 5.5 to about 7.0; (iii) a calcium salt in a concentration of at least 200 mM is both novel and unobvious over the prior art of record.

The IDS filed on April 6, 2011 has been considered. None of the references submitted on the IDS either anticipates or renders obvious the claimed invention. The closest art filed with the IDS is Mekka et al (WO 97/19687). The art teaches the preparation and use of liquid formulations of plasma proteins, stable liquid formulations of Factor VIII and Factor IX that can be administered by injection (see abstract). The

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reference teaches dependence of Factor IX stability on CaCl_2 concentration. Factor IX are present at 100 units/mL in 0.01 Histidine, 0.1 M NaCl, pH 6.8 with varied concentrations of CaCl_2 ranging from 0-10 mM. The reference teaches that the stability rose quickly by 2 mM, peaked at 5 mM, and leveled through 10 mM CaCl_2 (see Fig 1 and page 11). Figures 9-11 show stability of protein formulation at 10 mM, 30 mM and 100 mM CaCl_2 concentrations (see Figs 9-11 and page 13). The highest amount of calcium chloride used in the reference is 100 mM. From the teachings of the reference, one of ordinary skill in the art would not be motivated to increase the calcium chloride concentration to at least 200 mM. Therefore, the art does not anticipate or renders obvious the claimed invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

3. Claims 1-4, 6-7, 11, 14-19, 21-26 and 29-31 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie Ha/
Primary Examiner, Art Unit 1654